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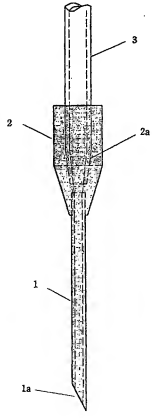
(54) Title: BLOOD VESSEL NEEDLE USING BIODEGRADABLE MATERIALS



(57) Abstract: The present invention is made for achieving a needle for intravascular injection made of biodegradable compounds, which is configured to have sufficient hardness to pierce the skin of a patient without using a metal guide needle, and to allow the needle to soften once it is inserted into a blood vessel, due to a patient's body temperature, and moisture and enzymes present in the blood vessel. The needle of the present invention, requiring no metal guide needle, comprises a needle tube including a tubular body and a needle formed at a tip of the tubular body, and a hub coupled to an end of the needle tube opposite to the tip of the tubular body. The needle tube is made of a composition including biodegradable synthetic high-molecular weight compounds and 1 to 10 percent by weight of starch, based on the total weight of the composition.

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BLOOD VESSEL NEEDLE USING BIODEGRADABLE MATERIALS

Technical Field

The present invention relates to a medical needle used for intravascular injection, and more particularly to an intravascular injection needle made of biodegradable compounds, which is configured to have sufficient hardness to pierce the skin of a patient without using a metal guide needle, and to allow the needle to soften once it is inserted into a blood vessel due to a patient's body temperature, and moisture and enzymes present in the blood vessel.

Background Art

In general, an intravascular needle tube is used to continuously supply a medical fluid such as infusion solution or injection into a blood vessel of a patient. This kind of needle tube is conventionally referred to as an infusion set or catheter.

Unlike general needles, the intravascular needle tube, as one of fundamental parts of the infusion set, comprises a metal guide needle and a synthetic resin tube (i.e. Teflon tube) adapted to be fitted around the metal guide needle, in order to prevent accidental damage to a blood vessel due to normal patient movement. The metal guide needle has a function of initial penetration of the skin and blood vessel in order to lead the synthetic resin tube surrounding it into the blood vessel. The synthetic resin tube, formed as a flexible synthetic resin tube, is adapted to be inserted into the blood vessel while coming into close contact with the outer surface of the metal guide needle at its inner surface. After being inserted, the synthetic resin tube is coupled with an infusion solution tube so as to supply infusion solution or injection into the blood vessel.

In the conventional needle tube for intravascular injection constructed as stated above, the metal guide needle is adapted to be discarded after it completes its function of leading the synthetic resin tube into the blood vessel. Such disposal of the metal guide needle increases the volume of hazardous waste and, furthermore, increases a price of a disposable intravascular injection needle. Further, in order to allow the metal guide needle to be inserted therein, the synthetic resin tube is provided with a metal eyelet. The formation of such a

metal eyelet complicates the overall manufacturing process of the synthetic resin tube.

When the needle tube for intravascular injection is withdrawn from the blood vessel following penetration of the blood vessel and then connected with the infusion solution tube, there is a potential hazard associated with sudden gush of blood through a plastic tube from the blood vessel. In addition, during the removal of the metal guide needle, a surgeon may be pricked by the needle through carelessness, thus possibly becoming infected with fatal diseases.

Representative ones, among conventional biodegradable high-molecular weight compounds suitable for use as biomedical compounds, are polylactide(PLA) and polyglycolide, or copolymers thereof. These biodegradable high-molecular weight compounds are actually used in the medical field as surgical sutures, due to their high biocompatibility. Currently, active research and development is targeting artificial skin, injury-treatment accelerators and so on using chitosan as a natural high molecular weight compound.

Nevertheless, no needles for intravascular injection made of biodegradable high-molecular weight compounds have been reported yet, and thus it can be said that the present invention is a novel device.

Disclosure of the Invention

Therefore, the present invention has been made in view of the above problems, and it is an object of the present invention to provide a needle for intravascular injection, which is configured to have sufficient hardness to pierce the skin and blood vessel of a patient at room temperature, and to increase the flexibility of a needle tube, while losing the sharpness of a tip of the needle tube due to a patient's body temperature, and moisture and enzymes present in blood once it is inserted into a blood vessel.

In accordance with the present invention, the above and other objects can be accomplished by the provision of a needle for intravascular injection comprising a needle tube including a tubular body and a needle formed at a tip of the tubular body; and a hub coupled to an end of the needle tube opposite to the tip of the tubular body, the needle tube being made of a composition including biodegradable synthetic high-molecular weight compounds and 1 to 10 percent by

weight of starch, based on the total weight of the composition. The needle of the present invention is adapted to soften within a patient's body.

In the needle of the present invention constructed as stated above, the needle is integrally formed at the tip of the tubular body, unlike a general intravascular injection needle, thereby eliminating the use of a conventional metal guide needle. The conventional metal guide needle is an essential part of the general intravascular injection needle (i.e. catheter).

The needle tube according to the present invention is made of a composition including at least two kinds of biodegradable synthetic high-molecular weight compounds and starch. The starch is added to the biodegradable synthetic high-molecular weight compounds so that starch particles having a diameter of not more than 20 micrometers are contained in the high-molecular weight matrix constituting the tube. The needle tube constructed as described above shows similar hardness and strength to the metal guide needle during its initial injection and penetration of a blood vessel. Then, once the needle tube is inserted into the blood vessel, the needle tube is adapted to soften, thereby having a similar flexibility to a synthetic resin tube.

The biodegradable high-molecular weight compounds may be polylactide(PLA) (or copolymers thereof), and polybutylenesuccinate(PBS) (or copolymers thereof).

The polylactide(PLA) (or copolymers thereof) has a high degree of hardness and strength, thereby allowing the needle tube containing polylactide to easily pierce the skin of a patient. The polybutylenesuccinate(PBS) (or copolymers thereof) serves to improve processibility of polylactide(PLA) and to secure softening of the needle tube when the needle tube is inserted into a patient's body, thereby facilitating free movement of a patient.

Considering the biodegradable high-molecular weight compounds, except the starch, a weight ratio of polylactide(PLA) (or copolymers thereof) to polybutylenesuccinate(PBS) (or copolymers thereof) may be selected appropriately in the range of 90:10 to 50:50, in accordance with a size and use purpose of the needle tube. If the content of polylactide(PLA) (or copolymers thereof) is more than 90 percent by weight, hardness of the needle tube is increased, while processibility and flexibility thereof are reduced. On the other hand, if the content of polylactide(PLA) (or copolymers thereof) is not more than 50 percent

by weight, even hardness of the needle tube is reduced, thereby making the needle tube fail to pierce the skin of a patient.

Therefore, a most preferable weight ratio of polylactide(PLA) (or copolymers thereof) to polybutylenesuccinate(PBS) (or copolymers thereof) is in the range of 80:20 to 65:35. In this range, the needle tube shows a high level of hardness and processibility.

Considering the starch as one component of the needle tube, it is adapted to be dissolved gradually when the needle tube is inserted into the blood vessel due to moisture and enzymes present in a blood vessel, thereby increasing the flexibility of the needle, while reducing the sharpness of the needle.

The used starch is mixed with the biodegradable high-molecular weight compounds to modify them, thereby obtaining in the form of thermoplastic starch(TPS). The content of starch is in the range of 1 to 10 percent by weight, based on the total weight of the needle tube.

If the content of starch is not more than 1 percent by weight, it is impossible to achieve a function of the starch. On the other hand, if the content of starch is more than 10 percent by weight, the processibility and mechanical properties of the needle tube are deteriorated.

Therefore, where the content of starch is preferably in the range of 3 to 5 percent by weight, it is possible to achieve the needle tube having a high level of processibility and optimal features able to achieve the objects of the present invention.

Brief Description of the Drawings

The above and other objects, features and other advantages of the present invention will be more clearly understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

Fig. 1 is a schematic view illustrating a needle for intravascular injection in accordance with the present invention.

Best Mode for Carrying Out the Invention

Examples

Now, preferable examples of the present invention will be described as follows.

Example 1

A needle tube was manufactured by mixing polylactide, polybutylenesuccinate, and thermoplastic starch in the weight ratio of 65:30:5, and extruding the resulting mixture to have a certain outer diameter and thickness using a certain extruding apparatus.

Then, an animal experiment was performed for inserting the manufactured needle tube into an ear blood vessel of a rabbit as a laboratory animal. As a result, it was found that the manufactured needle tube easily pierced the skin of the rabbit. In addition, it was confirmed that the sharpness of the distal portion of the needle tube was reduced and the needle tube was softened once it was inserted into the blood vessel.

Example 2

A needle tube was manufactured by mixing polylactide, polybutylenesuccinate, and thermoplastic starch in the weight ratio of 75:22:3, and extruding the resulting mixture to have the same outer diameter and thickness as those of Example 1 using the extruding apparatus of Example 1.

Then, an animal experiment was performed for inserting the manufactured needle tube into an ear blood vessel of a rabbit as a laboratory animal, in the same manner as Example 1. As a result, it was found that the manufactured needle tube easily pierced the skin of the rabbit. In addition, it was confirmed that the sharpness of the distal portion of the needle tube was reduced and the needle tube was softened once it was inserted into the blood vessel.

Example 3

A needle tube was manufactured by mixing polylactide, a polybutylenesuccinate-butyleneadipate copolymer, and thermoplastic starch in the weight ratio of 75:22:3, and extruding the resulting mixture to have the same outer diameter and thickness as those of Example 1 using the extruding apparatus of Example 1.

Then, an animal experiment was performed for inserting the manufactured needle tube into an ear blood vessel of a rabbit as a laboratory animal, in the same

manner as Example 1. As a result, it was found that the manufactured needle tube easily pierced the skin of the rabbit. In addition, it was confirmed that the sharpness of the distal portion of the needle tube was reduced and the needle tube was softened once it was inserted into the blood vessel.

Example 4

A needle tube was manufactured by mixing a polylactide-glycolide copolymer, polybutylenesuccinate, and thermoplastic starch in the weight ratio of 70:25:5, and extruding the resulting mixture to have the same outer diameter and thickness as those of Example 1 using the extruding apparatus of Example 1.

Then, an animal experiment was performed for inserting the manufactured needle tube into an ear blood vessel of a rabbit as a laboratory animal, in the same manner as Example 1. As a result, it was found that the manufactured needle tube easily pierced the skin of the rabbit. In addition, it was confirmed that the sharpness of the distal portion of the needle tube was reduced and the needle tube was softened once it was inserted into the blood vessel.

As may be seen from the results of foregoing examples, in order to allow the needle tube to pierce the skin of a patient, the polylactide(PLA) constituting the needle tube must have a content at least exceeding 65 percent by weight, based on 100 percent by weight of the needle tube. On the other hand, in order to increase processibility of the needle tube as well as to prevent the needle tube from being broken, the polylactide(PLA) also must have a content not exceeding 80 percent by weight. In relation to the thermoplastic starch(TPS), it must have a content not exceeding 10 percent by weight, based on 100 percent by weight of the needle tube, in order to secure sufficient processibility of the needle tube.

More preferably, the content of polylactide(PLA) (or copolymers thereof) may be in the range of 80 to 65 percent by weight, the content of polybutylenesuccinate(PBS) (or copolymers thereof) may be in the range of 20 to 35 percent by weight, and the content of thermoplastic starch(TPS) may be in the range of 1 to 10 percent by weight. These contents are based on 100 percent by weight of the needle tube.

As a result of clinical tests, the needle tube, constructed according to above examples, is softened rapidly within 3 to 5 minutes once it is inserted into the blood vessel of a patient, and then the inserted needle tube usually stays in the blood vessel

from 3 hours to 1 week until it is dissolved completely. Similarly, the needle tube, viewed from the animal experiment, is softened at a constant rate starting from a rapid softening time point.

Referring to the processing method of the needle tube in accordance with the present invention, the needle tube, made of a composition as stated above, may be processed by an injection molding method using a mold shaped into the form of the needle tube, or by an extrusion molding method using a tube extruder. In the case of extrusion molding, the used tube extruder employs the same manner as a general straw extruder, except that it is provided with a die having a diameter of not more than 5 mm and configured so that an extruding speed and a holding device thereof are accurately controlled.

Specifically, where the needle tube is manufactured using the extrusion molding method, it is necessary to process the end of the needle tube using a separate cutting device mounted in the extruder, while the injection molding method of the needle tube does not need a separate post-treatment.

A representative one of the cutting devices used for the processing of the needle tube is a cutting device adapted to rotate a blade in a diagonal direction, or a cutting device adapted to scan a laser beam at a constant angle.

Fig. 1 is a schematic view illustrating a needle for intravascular injection in accordance with the present invention. Referring to Fig. 1, the needle for intravascular injection comprises a needle tube, manufactured by extruding certain compounds as stated above. The needle tube includes a tubular body 1 and a needle 1a formed at the tip of the tubular body 1. A hub 2 is manufactured separately and then coupled to the end of the needle tube opposite to the tip of the tubular body 1. Specifically, the end of the needle tube opposite to the tip of the tubular body 1 is bonded inside a trumpet bell mouth 2a of the hub 2. The trumpet bell mouth 2a of the hub 2 has a tapered shape and is adapted to perfectly receive an infusion solution tube 3.

The hub 2 may be made of various compositions, so long as it is made of a biodegradable high-molecular weight compound.

According to the present invention, the hub 2 and needle tube including the tubular body 1 and needle are formed into single body, via the injection molding of certain compound as stated above. Thus, since the needle for intravascular injection is manufactured through only one molding process, a price of products can be reduced by virtue of simplification of manufacturing process.

The needle for intravascular injection according to the present invention is configured so that the needle is integrally formed at the plastic tubular body adapted to soften in infusion solution. Namely, the present invention has a technical feature of not using a conventional metal guide needle, thereby allowing the needle to be formed into various optimal shapes suitable for various uses thereof. The configuration of the needle as described above is a representative configuration, given purely by way of example for explaining the present invention, and is not intended to exclude other possible configurations.

Industrial Applicability

As apparent from the above description, the present invention provides a needle for intravascular injection, which is formed by adding starch to biodegradable compounds. The obtained needle has sufficient hardness to pierce the skin and blood vessel of a patient at room temperature. In addition, once the needle tube is inserted into the blood vessel, the flexibility of the needle tube can be increased, while the sharpness of needle portion can be reduced, due to a patient's body temperature, and moisture and enzymes present in blood.

According to the present invention, by not using a metal guide needle, which has been used essentially in existing catheters or infusion sets, it is possible to reduce the volume of hazardous waste, to reduce the manufacturing cost thereof, and to reduce safety hazards due to the metal needle. In addition, since the needle tube of the present invention is inserted into the body of a patient while being directly coupled with an infusion solution tube, it is possible to effectively solve a problem of leakage of blood during the coupling of the infusion solution tube.

Although the preferred embodiments of the present invention have been disclosed for illustrative purposes, those skilled in the art will appreciate that various modifications, additions and substitutions are possible, without departing from the scope and spirit of the invention as disclosed in the accompanying claims.

Claims:

1. A needle for intravascular injection, requiring no metal guide needle, comprising:

a needle tube including a tubular body and a needle formed at a tip of the tubular body; and

a hub coupled to an end of the needle tube opposite to the tip of the tubular body,

the needle tube being made of a composition including biodegradable synthetic high-molecular weight compounds and 1 to 10 percent by weight of starch, based on the total weight of the composition.

2. The needle for intravascular injection as set forth in claim 1, wherein the synthetic high-molecular weight compounds are polylactide(PLA) and polybutylenesuccinate(PBS) in a weight ratio of 90:10 to 50:50.

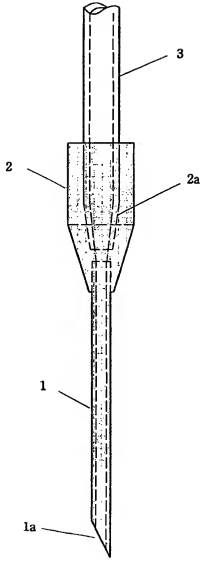
3. The needle for intravascular injection as set forth in claim 1, wherein the synthetic high-molecular weight compounds are a polylactide copolymer and a polybutylenesuccinate copolymer in a weight ratio of 90:10 to 50:50 .

4. The needle for intravascular injection as set forth in claim 1, wherein the needle tube including the tubular body and needle, and the hub coupled to the tubular body are formed into single body made of the composition including the synthetic high-molecular weight compounds and starch.

5. The needle for intravascular injection as set forth in claim 1, wherein: the needle tube, including the tubular body and needle, is made of the composition including the synthetic high-molecular weight compounds and starch; and

the hub is made of other compositions and then attached to the needle tube.

FIG. 1



INTERNATIONAL SEARCH REPORT

International application No.
PCT/KR03/01457

A. CLASSIFICATION OF SUBJECT MATTER

IPC7 A61M 5/158

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 : A61M, A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
KR, JP : IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
KIPASS, KR, ((biodegradable <near/3> needle) <or> (biodegradable <and> starch <and> PLA <and> PBS))

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2002/0022855 A1 (Bobroff et al.) 21 Feb. 2002 See 5 p. [0090], 6 p.[0091]	1, 4-5
Y	KR 2001-0060152 A (SEO Kwan-Ho) 06 Jul. 2001	1, 4-5
A	FR 2687320 A1 (Paul et al.) 20 Aug. 1993	1-5
A	KR 1999-0022514 A (Dakeda Yakuhin KK co.) 25 Mar. 1999	1-5
A	US 5858244 A (Rodgers et al.) 12 Jan. 1999	1-5

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
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